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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,584	12/20/2001	Michael V. Chobotov	24641-1120	4975

20350 7590 09/30/2004

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/029,584

Applicant(s)

CHOBOTOV ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-20,22-29,31-37,62-64,66,67,69,71 and 74-95 is/are pending in the application.
- 4a) Of the above claim(s) 7-10,26-29,36 and 79-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,12-20,22-25,31-35,37,62-64,66,67,69,71,74-78 and 83-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 8/23/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/029,584 is acceptable and a RCE has been established. An action on the RCE follows.

### ***Response to Amendment***

2. The amendment filed 6/9/04 has been entered. The amendments to the claims and changes made to Figure 25A have been approved by the examiner. In addition to claims 30, 65, 70, 72 and 73, which applicant states are canceled in the REMARKS section of the amendment, it appears from the listing of claims that claim 68 has also been canceled. Claims 91-95 have been added, and claims 7-10, 26-29, 36 and 79-82 remain withdrawn from consideration. The claims currently pending are 1, 3-10, 12-20, 22-29, 31-37, 62-64, 66, 67, 69, 71 and 74-95. The claims being considered for further examination on the merits are 1, 3-6, 12-20, 22-25, 31-35, 37, 62-64, 66, 67, 69, 71, 74-78 and 83-95.

### ***Claim Objections***

3. Claim 67 is objected to because of the following informalities: claim 67 requires the generally tubular flexible material portion to comprise a plurality of layers when claim 62, on which it depends, already requires it. The limitation should be deleted to avoid redundancy. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-5, 12-20, 22-24, 31-35, 69, 71, 74-77, 83-90 and 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. (USPN 6,149,681, as cited in previous office action) in view of McDermott et al. (USPN 6,312,462 as cited in applicant's IDS).

Houser et al. discloses an implantable vascular graft with all the elements of claims 1, 19, 20, 34, 35, 69, 74, 90, 93 and 95, but is silent to the flexible material portion comprising a plurality of layers and the flap of flexible material being secured to another layer. See Figure 9 for at least one flap (92) of the flexible material being folded back and secured to itself to form a loop portion about an expandable (column 7, lines 20-22 and column 8, lines 7-8) transversely oriented member/connector member/member (90). The method of forming a joint disclosed in column 8, lines 33-51 of fixing a flap (92) of the flexible material portion (80) about at least a portion of the transversely oriented member/connector member (90) provides a configuration that is inherently capable of transferring the tensile force on the transversely oriented member/connector member into a shear component of force on the fixed portion of the flap. McDermott et al. teaches an implantable vascular graft with a flexible material portion comprising two layers (34, 36). Inflatable channels that are circumferential rings (claims 71 and 94; see Figure 5) are formed between the two layers so that following insertion of the graft into a vessel, fluid can be injected between the layers into the channels to conform the graft to the

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vessel wall. See column 3, lines 8-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of McDermott et al. to modify the vascular graft of Houser et al. by having the flexible material portion comprise two layers with circumferential ring channels formed therebetween in order to conform the graft to the vessel wall upon injection of a fluid in the channels. This will help prevent blood from leaking around the graft. When the two-layered flap of flexible material is folded back to form a loop portion about the transversely oriented member/connector member/member, the flap will comprise a layer (outer layer 36), that is secured to itself and another layer (inner layer 34).

Claims 3, 4, 22, 23, 75 and 76, see column 7, lines 19-20 and 50-58 for transversely oriented member/connector member comprising a material, nickel titanium, having a higher strength relative to the strength of the flexible material.

Claims 5, 24 and 77, see column 8, lines 47-49 for securing the flap by bonding with an adhesive to the flexible material of the graft.

With respect to claims 12, 31 and 83, Houser et al. does not disclose the at least one flap being specifically about 1 to 25 square millimeters. In Figure 8 of Houser et al., it is clear that the length of the flap (92) corresponds to the length of the top of the transversely oriented member/connector member/member around which the loop is formed. Because the length of top of the transversely oriented member/connector member/member determines the circumference of the vascular graft formed, variation in the length will provide grafts of different diameters made for different sized vessels. A graft having a small diameter will therefore have a small flap area. Because the size of the graft will depend on the needs of the individual patient, it is obvious that

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the flap area required by claims 12, 31 and 83 will be met by the implantable vascular graft of Houser et al.

Claims 13, 14, 32, 33, 84 and 85, see Figure 8 and column 8, lines 39-51 for the joint comprising a plurality of flaps, one flap around each of the top and bottom transversely oriented member/connector member/member (90), folded back and secured to itself to form loop portions about the transversely oriented member/connector member/member.

Claims 15-18 and 86-89, see abstract, column 7, lines 20-22 and column 8, lines 7-8 for transversely oriented member/member limitations.

6. Claims 6, 25, 37 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. and McDermott et al. as applied to claims 5, 24, 35 and 77 above, and further in view of Edwin et al. (USPN 6,245,099 as cited in previous office action).

Houser et al., as modified by McDermott et al., discloses an implantable vascular graft with all the elements of claims 5, 24, 35 and 77, but is silent to the adhesive being FEP or PFA, as required by claims 6, 25, 37 and 78 and of the flexible material portion comprising ePTFE, as also required by claim 37. Edwin et al. teaches a graft wherein FEP is introduced between layers of ePTFE in order to selectively bond the layers together. See column 8, lines 40-45. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Edwin et al. to make the flexible material portion of Houser et al. from the material well known in the vascular graft art, ePTFE, and to use FEP as the adhesive in Houser et al. to secure the flap to flexible material because it is well known in the art to effectively bond

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ePTFE to ePTFE. This will prevent the flap from separating from the flexible material during use.

7. Claims 62, 64, 66, 67 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne (USPN 6,558,414 as cited in applicant's IDS) in view of McDermott et al.

Layne discloses an endovascular graft with all the elements of claims 62 and 91, but is silent to the flexible material portion comprising a plurality of layers and the flap of flexible material being secured to another layer. See Figure 4 and columns 3-4, lines 57-6 for a generally tubular flexible material portion (20) and a serpentine expandable member (30) circumferentially oriented about a circumference of the generally tubular flexible material portion (20). The expandable member (30) is secured to the generally tubular flexible material portion with a joint that includes at least one flap (50) of the flexible material folded back to form a loop portion about the serpentine expandable member (30). See column 4, lines 51-56 for the flap of flexible material comprising a layer that is secured to itself. McDermott et al. teaches an implantable vascular graft with a flexible material portion comprising two layers (34, 36). Inflatable channels that are circumferential rings (claims 64, 66; see Figure 5) are formed between the two layers so that following insertion of the graft into a vessel, fluid can be injected between the layers into the channels to conform the graft to the vessel wall. See column 3, lines 8-19. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of McDermott et al. to modify the vascular graft of Layne by having the flexible material portion comprise two layers with circumferential ring channels formed therebetween in order to conform the graft to the vessel wall upon injection of a fluid in the

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channels. This will help prevent blood from leaking around the graft. When the two-layered flap of flexible material is folded back to form a loop portion about the serpentine expandable member, the flap will comprise a layer (outer layer 36), that is secured to itself and another layer (inner layer 34). With respect to claim 67, see the rejection to claim 62.

8. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne and McDermott et al. as applied to claim 62 above, and further in view of Lombardi (WO 01/58384 A1).

Layne, as modified by McDermott et al., discloses an endovascular graft with all the elements of claim 62, but is silent to the additional limitation of at least some of the apices in the first set of apices further comprising connector elements that extend in a direction substantially parallel to the longitudinal axis of the generally tubular flexible material portion and beyond an edge of the generally tubular flexible material portion, as required by claim 63. See Figures 2 and 4 for the serpentine expandable member comprising first and second sets of apices directed in substantially opposite directions. Lombardi teaches a stent-graft wherein the stent apices (70) comprise connector elements (74) that extend in a direction substantially parallel to the longitudinal axis of the stent and have spherical beads (76) welded thereto. See Figures 13-15 and pages 19-20, lines 20-3. By virtue of the rounded surface and greater thickness of the spherical bead (76) relative to the stent struts (54), the apices (70) defining the end of the stent are less likely to cause trauma in the bodily tissue in which the apices (70) are embedded, than if the connector elements (74) and beads (76) were absent. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lombardi



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to modify the first set of apices of Layne by including connector elements that extend in a direction substantially parallel to the longitudinal axis of the generally tubular flexible material portion and to weld spherical beads having a thickness greater than the thickness of the serpentine expandable member to the connector elements in order to reduce the likelihood of the first set of apices causing trauma to the vessel in which it is implanted. Because at least some of the first set of apices of Layne are exposed (not completely enclosed by the flexible material), the connector elements with beads extending therefrom will extend beyond an edge of the generally tubular flexible material portion.

9. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne in view of McDermott et al. as applied to claim 91 above, and further in view of Edwin et al.

Layne, as modified by McDermott et al., discloses an endovascular graft with all the elements of claim 91, but is silent to the additional limitation of the serpentine expandable member comprising a self expanding stent, as required by claim 92. See column 3, lines 18-19 for the serpentine expandable member being a metal stent. Edwin et al. teaches that self-expanding stents have an inherent resiliency that allows them to recover once a compressive force that results in deformation is removed, as opposed to balloon-expandable stents that deform and do not recover once compressive forces exceed their hoop strength. See column 5, lines 20-33. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Edwin et al. to make the metal stent of Layne self-expanding so that it can recover once a compressive force that results in deformation is removed.

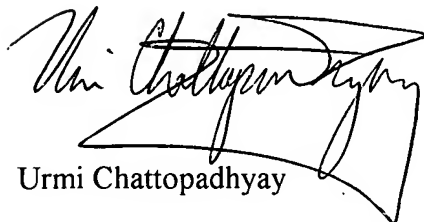
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***Response to Arguments***

10. Applicant's arguments with respect to claims 1, 3-6, 12-20, 22-25, 31-35, 37, 62-64, 66, 67, 69, 71, 74-78 and 83 have been considered but are moot in view of the new ground(s) of rejection.

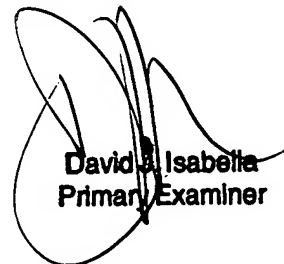
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David A. Isabella  
Primary Examiner